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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,264	11/28/2000	Andrew A. Welcher	01-668	6658

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/729,264	WELCHER ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10,48,57 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10,48,57-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Final Rejection

Claims 1-8, 10, 48 and 57-58 are pending.

Applicant's traversal and the amendment to claims 1, 2, 3, and 8 in paper filed on 1/31/05 is acknowledged and considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 10, 48, and 57-58 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a substantial or well-established utility.

The specification discloses a polynucleotide sequence, which encodes a B7-like polypeptide as set forth in SEQ ID NO: 2, 4, or 6. The specification further discloses an isolated nucleic acid sequence encoding a protein having B7-like activity (SEQ ID NO: 1, 3, or 5). The specification fails to disclose any particular function or biological significance for the claimed B7-like nucleotide sequences.

The specification contemplates using B7-like polynucleotides for producing knock-out or knock-in non-human animals for drug candidate screening (page 75). The specification further contemplates that exposure of said animals to a drug may decrease or increase expression of the protein encoded by a B7-like gene and may be associated with a disease or a pathological condition. The specification further contemplates using DNA microarrays to identify and validate B7-like genes in disease and as targets for therapeutics molecular toxicology of B7-like

molecules and inhibitors thereof; stratification of populations and generation of surrogate markers for clinical trials, and enhancing B7-like small molecules drug discovery by aiding in the identification of selective compounds in high throughput screens (page 76). The specification contemplates using B7-like genes or products directly or indirectly made from the gene to treat diagnosis, ameliorate or prevent acute or chronic disease associated with T-cell function (pages 95-98).

The claims are drawn to a polynucleotide sequence encoding a B7-like protein, which has no determined function or biological activity. At the time the invention was made, it was known that the function a B7 polypeptide was very diverse, and the B7 family of co-stimulatory molecules comprises B7.1 and B7.2 proteins, both of which can interact with two receptors, CD28 and CTLA-4, that are expressed by T cell proliferation, increasing evidence indicates that they may not deliver identical signals to T cells, and that they may skew Th1 and Th2 phenotypes (Li et al. Human Immunology, Vol. 61: 486-498, 2000). The as-filed specification provides no nexus between the 'association' of the claimed B7-like polynucleotide sequences with the B7 family of co-stimulatory molecules. The specification does not define B7-like activity, a B7-like polypeptide or a B7-like gene.

With respect to using the claimed sequences or products made directly or indirectly from the sequences in either an *in vitro* or an *in vivo* screening assay comprising observing an increase or a decrease of the claimed B7-like gene products or another gene product, the specification does not teach what to look for as a result of an increase or a decrease B7-like expression. One skilled in the art would have to further experiment on the invention to determine what results are

observed with either an increase or a decrease in B7-like expression. In absence of the specification teaching what to look for in the assays, the claimed invention lacks utility.

In addition, with respect to using the claimed B7-like polynucleotide sequences or products made directly or indirectly from the sequences to treat diagnosis, ameliorate or prevent acute or chronic disease associated with T-cell function, the specification provides no evidence that the B7-like proteins are involved to T-cell function. The specification provides no evidence that the claimed polynucleotide sequences are associated with any specific disease. It would require further experimentation on the claimed invention/or products made directly or indirectly from the sequences to determine whether they were involved in T-cell function or any disease. Thus, the asserted utilities set forth above do not provide a benefit to the public in currently available form. See Ziegler, 992 F.2d at 1203, 26 USPQ2d 1600 (Fed. Cir. 1993).

At page 73, lines 7-9 of the specification, the protein encoded by SEQ ID NO: 14 (an ortholog of SEQ ID NO: 1, 3 and 5) showed seminal vesicle hyperplasia in a transgenic mouse, however, this is not a disclosure of how to use the polypeptide sequence set forth in SEQ ID NO: 2, 4 or 6 (or the DNA molecule set forth in SEQ ID NO: 1, 3 or 5). SEQ ID NO: 14 has 23-24% sequence identity with SEQ ID NO: 1, 3 or 5. The specification and the art of record are absent that seminal vesicle hyperplasia in a transgenic mouse whose genome comprises SEQ ID NO: 14 is considered a B7 activity. The office conducted a sequence search of the polypeptide sequences set forth in SEQ ID NO: 2, 4, and 6 against amino acid public databases and the results from the search did not display any sequence similarity with a known B7 protein. In addition, sequences with the closest sequence similarity with SED ID NO: 2, 4 or 6 were proteins with completely different functions than a known B7 function. For example, Neeper et al., teach

a polypeptide that functions as a cell surface receptor for advanced glycosylation end product (AGE) (JBC, Vol. 267, pp. 14998-15004, 1992). The polypeptide sequence taught by Neeper has 22.6% sequence similarity with amino acids 15-349 of SEQ ID NO: 2; 23.5% sequence similarity with amino acids 64-353 of SEQ ID NO: 4; 23.3% sequence similarity with amino acids 9-353 of SEQ ID NO: 6.

Since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. See also In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967) and In Brenner v. Manson, 383 US 519, 148 USPQ 689 (1966). Also see REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS: www.uspto.gov/web/menu/utility.pdf.

Applicant's arguments filed 1/31/05 have been fully considered but they are not persuasive because they have already been addressed in previous office actions. See office action mailed on 9/27/04.

Applicant argues that Exhibit A (sequence alignment of SEQ ID NO: 14 individually with SEQ ID NO: 2, 4, and 6) provides support for the claimed molecules having credible, specific, and substantial utility.

Applicant's argument is not found persuasive because SEQ ID NO: 14 does not read on claim 1 because the claim does not include any limitation that would read on SEQ ID NO: 14. In addition, the claimed invention is directed B-7 molecules and inducing seminal vesicle hyperplasia is not an art recognized activity of a B-7 polypeptide. Furthermore, the instant specification does not provide sufficient guidance and/or factual evidence that the regions in

SEQ ID NO: 14 that share substantial identity (<62%) to SEQ ID NO: 2, 4, and 6 are the regions for inducing seminal vesicle hyperplasia

In addition, with respect to applicant's assertion that "one of ordinary skill in the art would recognize that the polypeptides set forth in SEQ ID NO: 2, 4, or 6 could be used for example to develop agonists or antagonists useful in the treatment of reproductive disorders and proliferative disorders". The assertion is not found persuasive because other than the assertion, the applicant provides no guidance and/or evidence to support this assertion. Therefore, applicant's assertion regarding using the claimed molecules for developing agonists or antagonists useful for treatment of reproductive disorders and proliferative disorders is not compelling. See MPEP § 716.01(c).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10, 48, 57, and 58 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments filed 1/31/05 have been fully considered but they are not persuasive for the reasons set forth in the response to applicant's argument against the 101 rejection.

Claims 1-8, 10, 48, and 57-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation 'a nucleotide sequence that hybridizes to the complement of the nucleotide sequence of either (a) or (b) under conditions for hybridization and washing of 0.015M sodium chloride, 0.0015M sodium citrate at 65-68°C or 0.015M sodium chloride, 0.0015M sodium citrate, and 50% formamide at 42°C wherein the nucleotide sequence is at least 75% identical to the nucleotide sequence of either (a) or (b)' in step (c) of amended claims 1-3 is not supported by the as-filed specification. There appears to be no written description in the application as filed for the limitation in the amended claims. See MPEP § 2163.06. Page 27, lines 20-24 in the instant specification is cited by applicant for support of the amended claims, but this page does not disclose the limitation in claims 1-3 as amended. On page 27, lines 20-24, applicants teach: "Examples of "highly stringent conditions" for hybridization and washing are 0.015M sodium chloride, 0.0015M sodium citrate at 65-68°c or 0.015M sodium chloride, 0.0015M sodium citrate, and 50% formamide at 42°C". Page 27, lines 20-24 provides support for the limitation '"highly stringent conditions" for hybridization and washing are 0.015M sodium chloride, 0.0015M sodium citrate at 65-68°c or 0.015M sodium chloride, 0.0015M sodium citrate', but this page does not provide support for 'wherein the nucleotide sequence is at least 75% identical to the nucleotide of either (a) or (b)' in step (c) in the amended claims. The limitation is a

combination from two different parts of the specification. However, nothing in the specification would lead one to the particular combination set forth in the amended claims.

> "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."
>
> *Lockwood v. American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

Thus, it is apparent that the applicants at the time the invention was made did not intend or contemplate the nucleotide sequence cited in step (c) of the claims and claims dependent therefrom as part of the disclosure of their invention. There is no evidence in the specification that the applicants were in possession of the claimed nucleotide sequence as set forth in the claims, as it is now claimed, and claims dependent therefrom at the time the application was filed.

Applicant's arguments with respect to claims 1-8, 10, 48, and 57-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

AU1635